SCA 135
ACCURACY AND PRECISION OF MASIMO SET, AGILENT MERLIN, AND NELLCOR N-395 PULSE OXIMETERS IN PATIENTS UNDERGOING CARDIOPULMONARY BYPASS FOR CONGENITAL HEART DEFECTS

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Introduction: Patients undergoing congenital heart repair requiring cardiopulmonary bypass (CPB) frequently experience saturations below 90%. Pulse oximetry has become an integral part of perioperative management of these patients but in situations of poor peripheral perfusion or severe oxygen desaturation, accuracy and reliability are questionable.(1) The aim of this study was to compare the accuracy of three pulse oximeters with reported improved capabilities, Masimo SET, Agilent Merlin, and Nellcor N-395 in these patients.

Methods: Following IRB approval and informed consent, patients between the ages of 1 day to 53 years scheduled to undergo surgery for congenital heart disease requiring CPB were enrolled. Immediately after unconsciousness, three pulse oximeters (Masimo SET, Agilent Merlin, and Nellcor N-395) were attached to specified digits on a rotational basis to avoid bias regarding arterial and venous catheter location. Probes were shielded by black tape on each digit to avoid light interference and sensor to sensor optical cross-talk. Pulse oximeter derived oxygen saturations (SpO_2) and pulse rate were recorded and stored each second in a dedicated computer. A co-oximeter was used to determine arterial oxygen saturation (SaO_2) to compare with SpO_2 values at the following points: baseline (after induction), 10 minutes after protamine administration, sternal closure, 30 minutes after intensive care unit (ICU) arrival, and 30 minutes post-extubation. Agreement between SpO_2 and SaO_2 was assessed for each oximeter using the methods of Bland and Altman.(2) In all cases p-values d" 0.05 denoted statistical significance.

Results: Fifty-two patients were studied. Demographics and surgical characteristic are in the table. The median age was 2 years. Forty of the 52 patients (77%) had a period of circulatory arrest. Bland-Altman plots, showing the agreement between saturation measured by pulse oximeter and by co-oximeter is presented in the figure. Separate analyses were also performed for three groups defined using SaO_2 (>90%, 80%-90%, <80%). To assess whether the loss of measurement precision observed at low levels of SaO_2 differed significantly between pulse oximeters, a repeated measures analysis of covariance was employed. The bias ± precision of the Masimo SET, Agilent Merlin, and Nellcor N-395 were –0.3 ± 2.5, 0.0 ± 2.7 and 0.0 ± 2.8 at SaO_2 > 90%; –2.1 ± 4.2, –2.4 ± 8.0 and –1.3 ± 5.2 and at 80% ≤ SaO_2 ≤ 90% (p<0.05), and 3.5 ± 6.0, 3.6 ± 14.1 and 3.6 ± 8.4 at SaO_2 < 80% respectively.

Discussion: Findings demonstrate that the Masimo SET pulse oximeter has better precision than the Agilent and Nellcor oximeters when saturation is between 80% to 90% in patients undergoing cardiac surgery requiring CPB for congenital heart defects. Because our study was unable to obtain much information regarding saturations below 80%, additional studies need to be performed to assess accuracy in this range.

References:
1. Schmitt HJ, Schuetz WH, Proeschel PA, Jaklin C. Accuracy of pulse oximetry in children with cyanotic congenital heart disease. J Cardiothorac Vasc Anesth 1993;7:61-65.
2. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;1:307-310.

Demographic and Surgical Characteristics (N=52)

Characteristic	n (%)	Mean ± SD	Median
Age (years) [a]			
< 1	22 (42)		
1-5	13 (25)		
6-16	10 (19)		
>16	7 (13)		
Gender (males)	27 (52)		
Height (cm)		93.8 ± 42.1	82.4
Weight (kg)		19.9 ± 22.7	9.95
Room Air Saturation (%) a		80.8 ± 10.8	83
> 90	11 (22)		
80 - 89	20 (39)		
70 - 79	11 (22)		
< 69	9 (18)		
Duration of Bypass (min)		121.6 ± 57.1	110.5

[a] Missing for one patient. Statistics are presented on 51 patients.

Bland and Altman plot of agreement between saturation measured by Massimo SET, Nellcor N-395, Agilent Merlin pulse oximeters (SpO_2) and by co-oximeter (SaO_2). The solid line represents the mean difference (bias) and the dashed line represents the limits of agreement (mean difference ± 2 SD of the difference).